

Remarks

Reconsideration of this Application is respectfully requested.

Following entry of the amendments above, claims 19-40, 42-49, and 51-60 are pending in the application, with claims 19, 29, 39, and 48 being the independent claims. Subject to a restriction requirement (Paper No. 9), claims 61-66 have been canceled without prejudice or disclaimer of the subject matter therein. Claims 41 and 50 have also been canceled without prejudice or disclaimer of the subject matter therein. Applicants reserve the right to pursue the subject matter of these canceled claims in one or more divisional or continuation application(s). Claims 39 and 48 have been amended to cancel the "(b)" member of the Markush group. No new matter has been added by these amendments.

The specification has been amended to correct the date of deposit of ATCC Accession No. 75899, from September 28, 1994 to September 29, 1994. The ATCC deposit receipt and viability statement attached to the Statement Concerning the Deposited cDNA Clone, filed concurrently herewith, supports this amendment. The specification has also been amended to correspond the Brief Description of the Figures with the formal drawings.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Allowable Claims

Applicants note, with appreciation, the Examiner's indication that claims 19-38, 57 and 58 are allowable. Paper No. 11, page 6.

Drawings

In reply to the Draftspersons objections listed on the Form PTO 948 attached to Paper No. 11, Applicants submit Formal Drawings herein. It is noted that Applicants filed a Request to Approve Proposed Drawing Changes on April 8, 2002, to correct obvious errors. The attached Formal Drawings include these changes. This objection should be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

(1) Biological Deposit

Claims 39-43 and 48-52 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states that the invention is directed to antibodies which bind to proteins encoded by novel DNA sequences. Since the proteins are essential to the claimed invention, they must be

obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. The Examiner also states that if the proteins are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the disclosed DNA encoding protein of SEQ ID NO:2. Although the Examiner acknowledges that a deposit has been made, he states that it is unclear if the deposit was made under the guidelines of the Budapest Treaty and requests a Declaration by Applicant or a Statement by an attorney of record. *See*, Paper No. 11, page 3.

Applicants respectfully direct the Examiner's attention to page 34, lines 23-30, of the present specification, which states, in part, that "the deposit(s) referred to herein will be maintained under the terms of the Budapest Treaty on the International Recognition of the Deposit of organisms for purposes of Patent Procedure." The above notwithstanding, Applicants submit herewith a Statement Concerning the Deposited cDNA Clone, executed by an agent of record. An ATCC deposit receipt and viability statement is attached thereto.

In addition, at page 4 of Paper No. 11, the Examiner states that the specification should be amended to include various pieces of information about the deposit and to update the address for the ATCC.

Applicants believe that the relevant information for the deposit is already provided in the specification, at, for example, page 15, lines 1-7. Concerning the new address for the ATCC, Applicants respectfully direct the Examiner's attention to page 15, lines 1-4, of the present specification, which states, that the deposit of accession number 75899 was made on September 28 [sic:29], 1994 at the ATCC, and provides the new Manassas, VA address.

Applicants respectfully request that this rejection should be withdrawn in its entirety.

(2) Written Description: the term "mature portion of a protein"

At page 5 of Paper No. 11, the Examiner contends that claims 41, 48 and 50 recite a "mature portion of a protein" however, the specification fails to describe the portion of the protein which is the "mature" portion. The Examiner contends that the species "mature portion of a protein" is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. *See*, Paper No. 11, page 5.

Applicants' amendments or cancellation of the rejected claims render this rejection moot. It is respectfully requested that this rejection be withdrawn.

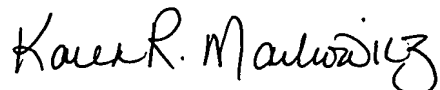
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Substitute the paragraph beginning on page 4, line 21, with the following paragraph:

The isolated nucleic acid molecules of the present invention comprise, or alternatively consist of, polynucleotide molecules encoding the native TR1 receptor polypeptide having the amino acid sequence shown in Figure 1 (SEQ ID NO:2) or the amino acid sequence encoded by the cDNA clone deposited in a bacterial host as ATCC Deposit Number 75899 on September [28] 29, 1994. The nucleotide sequence determined by sequencing the deposited native TR1 receptor clone, which is shown in Figure 1 (SEQ ID NO:1), contains an open reading frame encoding a polypeptide of 401 amino acid residues, including an initiation codon at positions 46-48 in Figure 1, with a leader sequence of about 21 amino acid residues, and a predicted molecular weight of about 46 kDa for the whole protein and about 44 kDa for the non-glycosylated mature protein. The amino acid sequence of the predicted mature native TR1 receptor protein is shown in Figure 1, amino acid residues about 22 to about 401 (SEQ ID NO:2).

Substitute the paragraph beginning on page 13, line 4, with the following paragraph:

Figure 9 (A-B) shows a screening assay (ELISA) of polyclonal rabbit anti-TR1 antibodies. Polyclonal rabbit anti-TR1 antibodies were prepared by Pocono Rabbit Farm & Laboratory, Inc. (Canadensis, PA 18325) according to standard [prptocol] protocol. The rabbit serum was tested by ELISA. In particular, the plates were coated with TR1 (labeled as TNFr batch HG02900-1-B) for 2 hours at room temperature or overnight at 4°C. After washing with PBS, they were blocked with PBS with 1% BSA and 0.5% sodium azide at 4°C overnight. The PBS-BSA was flicked out of the well and test supernatants were added and incubated for 1 hour at room temperature. After 3 washes with PBS, 50 ml of anti-rabbit IgG horseradish peroxidase conjugate (1:1000 dilution in PBS with 1% BSA) was added and incubated at room temperature for 0.5-1 hr. After 3 washes with PBS, the substrate solution for IgG horseradish peroxidase was added to the plate and incubated at room temperature for 10-30 minutes. The reaction was stopped by adding 50 ml of 0.1 M EDTA. The absorbance was read at 450 nm.

Substitute the paragraph beginning on page 14, line 28, with the following paragraph:

In accordance with an aspect of the present invention, there is provided an isolated nucleic acid molecule comprising, or alternatively consisting of, a polynucleotide encoding the predicted mature native TR1 receptor polypeptide having the deduced amino acid sequence of Figure 1 (SEQ ID NO:2) or for the mature native TR1 receptor polypeptide encoded by the cDNA of the clone which was deposited on September [28] 29, 1994 at the American Type Culture Collection, Patent Depository, 10801 University Boulevard, Manassas, VA 20110-2209, and given accession number 75899. The nucleotide sequence shown in Figure 1 (SEQ ID NO:1) was obtained by sequencing the HSABH13 clone deposited with the ATCC. The deposited clone is contained in the pBluescript SK(-) plasmid (Stratagene, LaJolla, CA).

Claims 41, 50, and 61-66 have been canceled.

39. (Once amended) An isolated antibody, which specifically binds a protein selected from the group consisting of:

- (a) a protein whose sequence consists of the amino acid sequence encoded by ATCC Deposit No. 75899;
- [(b) a protein whose sequence consists of the amino acid sequence of the mature polypeptide encoded by ATCC Deposit No. 75899;
- (c)] (b) a protein whose sequence consists of the amino acid sequence of 50 contiguous amino acids encoded by ATCC Deposit No. 75899; and
- [(d)] (c) a protein whose sequence consists of the amino acid sequence of 30 contiguous amino acids encoded by ATCC Deposit No. 75899.

48. (Once amended) An isolated antibody fragment, which specifically binds a protein selected from the group consisting of:

- (a) a protein whose sequence consists of the amino acid sequence encoded by ATCC Deposit No. 75899;
- [(b) a protein whose sequence consists of the amino acid sequence of the mature polypeptide encoded by ATCC Deposit No. 75899;
- (c)] (b) a protein whose sequence consists of the amino acid sequence of 50 contiguous amino acids encoded by ATCC Deposit No. 75899; and
- [(d)] (c) a protein whose sequence consists of the amino acid sequence of 30 contiguous amino acids encoded by ATCC Deposit No. 75899.